Development of Stimuli-Responsive Hydrogels for Controlled and Targeted Drug Delivery

SHORT SYNOPSIS

Submitted in partial fulfilment of the requirements of the degree of

DOCTOR OF PHILOSOPHY

by

Shashank Shekhar Pandey
Registration No. MRUCHDN012K240032

Under the supervision of

Dr. Arpit Sand
Professor
Department of Sciences (Chemistry)

Dr. Sudhir G. Warkar
Professor
Department of Applied Chemistry
Delhi Technological University

Department of Sciences (Chemistry)
School of Sciences

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Arpit Sand

Supervisor
Dr. Arpit Sand (Professor)
Department of Sciences (Chemistry)
Manav Rachna University

Co-Supervisor
Dr. Sudhir G. Warkar (Professor)
Department of Applied Chemistry
Delhi Technological University

ABSTRACT

This abstract explains the enormously increasing use of a sophisticated family of smart polymeric networks that can undergo bidirectional physicochemical modifications in response to external factors are stimuli-responsive hydrogels, especially those that are sensitive to environmental parameters like pH and temperature. These hydrogels are ideal for regulated and site-dependent drug delivery systems, or DDS, because of their perpetual swelling or deswelling activity, which is caused by changes in pH and heat stimuli.

Ionizable functional units (-COOH, -NH_2, -SO_3H) enable pH responsiveness, and thermosensitive elements (e.g., polymers with a lower critical solution temperature or LCST behaviour) enable the hydrogel to react to temperature changes. The acidic stomach, neutral bloodstream, moderately basic intestinal tract, and pathological areas like tumour cells with higher temperatures and altered pH are examples of physiological settings where both temperature and pH vary. This dual responsiveness is especially helpful in simulating these environments.

The design, synthesis, and assessment of stimuli-responsive (pH-, temperature-responsive) hydrogel systems to facilitate targeted drug administration are the main objectives of this study. To assess physical, thermal, and morphological characteristics, extensive characterisation methods, including FTIR (Fourier Transform Infrared Spectroscopy), SEM (Scanning Electron Microscopy), TGA (Thermogravimetric Analysis), XRD (X-Ray Diffraction) and UV(Ultraviolet) spectroscopy, along with swelling tests under different pH and temperature settings, are used. The polymer is a mixture of hydrogel in a previously tested proportion of synthetic and biologically degradable polymers. Since SAP (Superabsorbent Polymer) was selected with biocompatibility and biodegradability in mind, the usage of biodegradable polymers has been favoured in this field. The research aims to optimise the drug loading efficiency, stimuli-induced release kinetics, and biocompatibility of the hydrogel system.

By allowing for precise control over drug release, reducing systemic adverse effects, and increasing patient compliance, these environmentally responsive hydrogels hold great promise for improving therapeutic efficacy. For cutting-edge uses, including cancer treatment, colon-targeted administration, and adaptive oral drug delivery platforms, these systems show great promise.

Keywords: Stimuli-responsive hydrogel, superabsorbent polymers, pH-sensitive, thermo-responsive, drug delivery, controlled release, smart polymers, targeted therapy.

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1. Introduction

Three-dimensional cross-linked polymeric networks known as hydrogels are able to absorb and hold a lot of water without losing the integrity of their structures[1]. Because of their capacity to react dynamically to environmental elements, including pH and temperature, stimuli-responsive hydrogels have become known as "smart" materials[2]. These external stimuli cause the hydrogel network to undergo reversible physicochemical changes, which makes them ideal for sophisticated drug delivery applications.

Ionizable functional groups like -COOH, $-NH_2$, and $-SO_3H$ are present in pH-responsive hydrogels and can go through protonation or deprotonation based on the pH of the surrounding environment. The hydrogel matrix swells or contracts as a result of this ionisation's electrostatic repulsion within the polymer chains[3], [4]. Similar to this, polymers that display critical solution temperature characteristics like lower critical solution temperature (LCST), in which minute temperature changes can cause phase transitions in the polymer network and greatly alter its swelling properties, are used to create temperature-responsive hydrogels[5].

Temperature and pH have a significant impact on how drugs are released through these hydrogel systems. In physiological settings, both parameters differ in various parts of the human body. For example, the bloodstream is almost neutral (pH ~7.4), the stomach is extremely acidic (pH ~1.2), and the intestine is slightly basic (pH ~6.8-7.5), whereas the body temperature is kept at approximately 37°C[6]. Furthermore, pathological states, including tumour tissues and inflammatory areas, frequently exhibit slightly higher temperatures and varied pH, resulting in distinct micro-environments that can be used for regulated and targeted delivery of drugs[7]

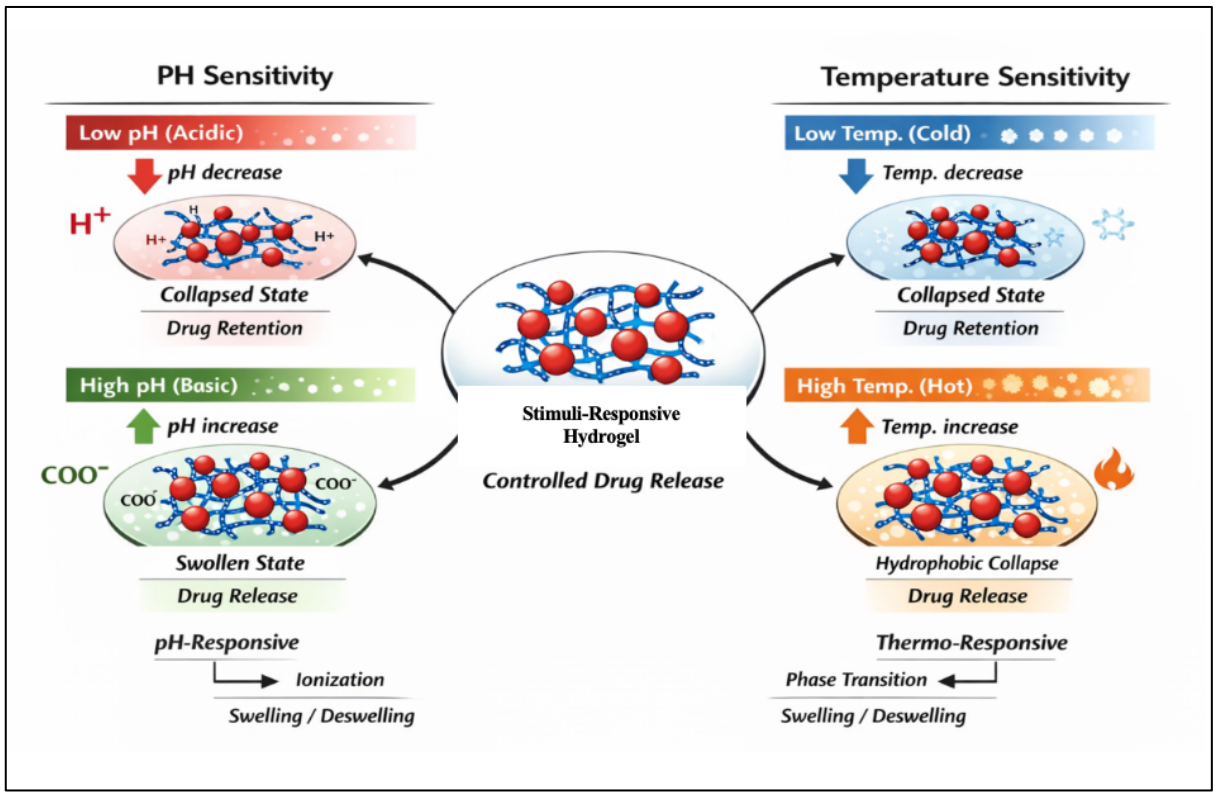
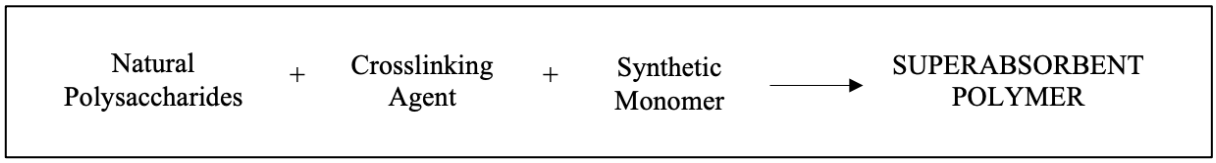


Fig. 1 Mechanism of Stimuli-Responsive Hydrogels: pH- and Temperature-Triggered Swelling Behaviour for Controlled Drug Release

Since they can intelligently alter their swelling behaviour and drug-release patterns in response to environmental signals, hydrogels sensitive to pH or temperature provide an extremely effective framework for site-specific drug delivery.

Reaction Structure for the proposed mechanism:



Superabsorbent polymers (SAPs) are mostly synthesised via free radical polymerisation, which is considered an effective and adaptable technique for creating crosslinked hydrogel networks. This process involves the polymerisation of hydrophilic monomers, such as acrylamide or acrylic acid, and even natural polysaccharides, in the presence of appropriate initiators and crosslinking agents[8]. Redox or thermal initiator substances, such as potassium persulfate,

break down during the reaction's initiation phase to produce extremely reactive free radicals. These radicals engage with the monomers' vinyl groups (C=C) to activate them for further chain reactions[9].

Long and linear polymer backbones are created during the propagating stage as a result of the activated monomer units' constant addition to the expanding polymer chain. A 3-D network structure is created concurrently by the introduction of covalent bonds between neighbouring polymer chains by crosslinking agents like N, N′-methylenebisacrylamide[10]. The distinctive swelling behaviour along with structural stability of the SAPs enables them to absorb and hold enormous amounts of water-based fluids without dissolving, are largely attributed to this crosslinked design.

To create SAP particles with the required physical characteristics, the hydrogel that is created after polymerisation is dried, and its size is reduced. Therefore, an array of chain initiation, chain propagation, and crosslinking reactions constitutes the overarching mechanism that determines the final material's physicochemical properties. The structural as well as functional characteristics of SAPs can be precisely tailored for particular uses by adjusting variables including monomeric composition, initiator amount, and crosslinking density. This is especially true for drug delivery systems wherein regulated swelling as well as release behaviour are crucial[1].

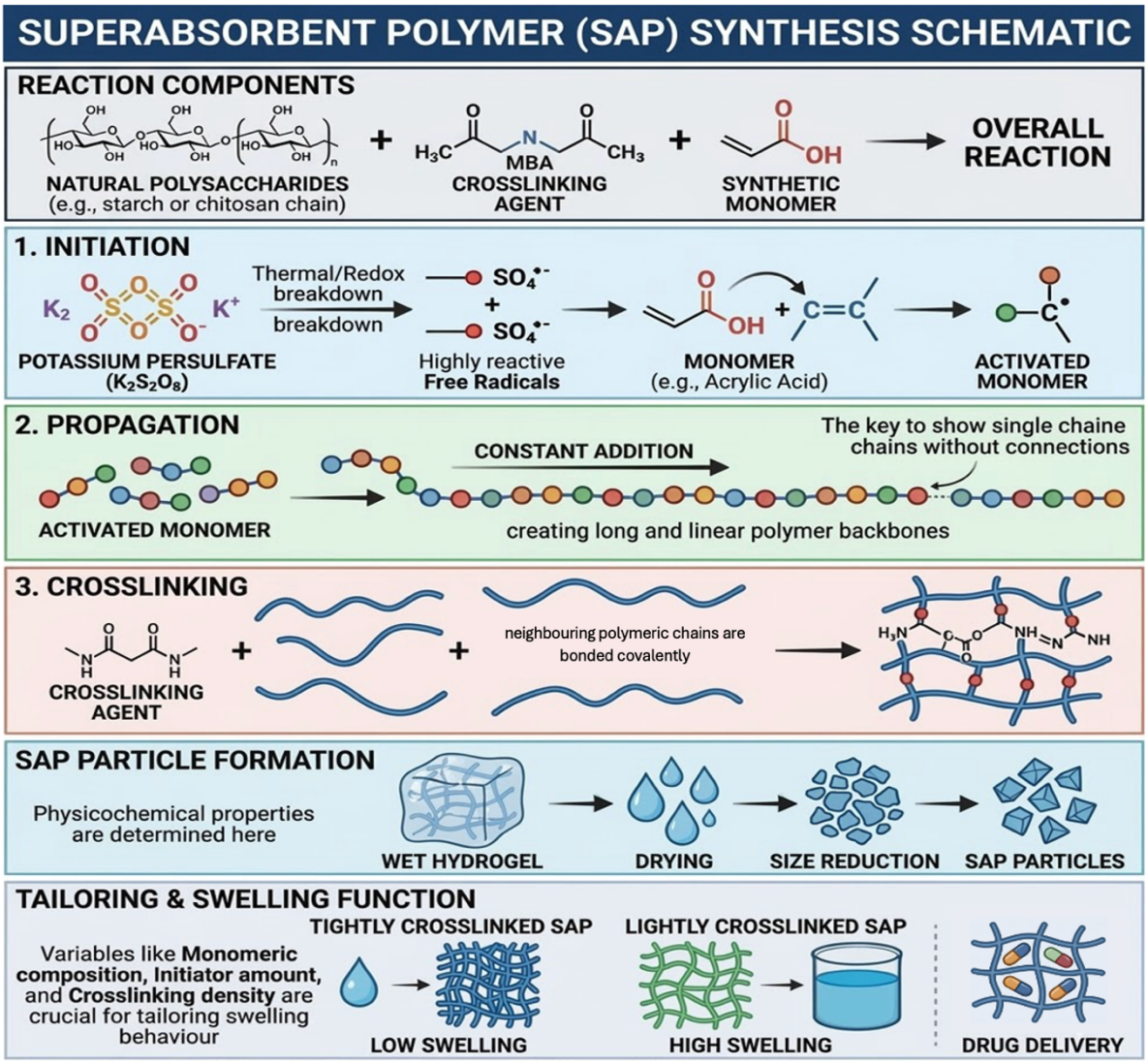


Fig. 2 Schematic Representation of Free Radical Polymerisation and Crosslinking in Superabsorbent Polymer (SAP) Synthesis for Drug Delivery Applications

2. Literature Review:

Due to their substantial swelling capacity, adjustable characteristics, and biocompatibility, superabsorbent polymers (or SAPs) and hydrogel-type systems have been thoroughly investigated for their potential in improved drug delivery applications. The development of stimuli-responsive SAPs that are capable of releasing medications under particular physiological conditions in a controlled manner has been the focus of recent research. For example, pH-regulated hydrogels comprised of poly(acrylic acid) or its analogues have shown great promise in colon-based drug delivery. The polymer expands under an alkaline intestinal

pH and remains crumbled in an acidic gastric environment, allowing for site-specific drug release[1].

For thermosensitive drug delivery systems, temperature-responsive polymers, especially those made from poly(N-isopropylacrylamide) (PNIPAM) have been extensively studied. These polymers can experience reversible phase shifts in response to body temperature because they have a lower critical solution temperature, or LCST, which helps regulate medication release profiles[2]. In a similar vein, SAPs that are sensitive to ionic strength and enzymes are being investigated for targeted administration in intricate biological settings.

The biodegradability, non-toxic nature, and biocompatibility of natural polymeric-based SAPs, such as those made from cellulose, alginate, and chitosan, have drawn interest. For instance, hydrogels based on chitosan have demonstrated exceptional mucoadhesive qualities, making them appropriate for transdermal, nasal, and oral drug delivery systems[11]. Nevertheless, these materials frequently have drawbacks like low mechanical strength and quick deterioration. In order to address these issues, scientists have created hybrid SAP systems that combine synthetic and natural polymers to improve structural stability while maintaining biocompatibility[12].

SAPs have also been extensively researched for applications involving regulated and sustained drug delivery. Diffusion, expanding, and polymeric relaxation processes, which can be adjusted through modifying crosslinking density and topology of networks, are the main mechanisms governing the release mechanism. Research has demonstrated that boosting crosslinking density slows drug release rates by improving mechanical strength while decreasing swelling capacity[10]. SAPs are exceptionally adaptable for creating personalised drug delivery systems because of this tunability.

Recent developments have also concentrated on nanocomposite SAPs, which integrate metallic, silica, or graphene oxide nanoparticles into the hydrogel matrix. These devices have better mechanical qualities, increased drug loading efficiency, and multifunctionality, including antibacterial and targeted delivery capabilities[13]. Additionally, site-specific and specific drug delivery has been demonstrated by smart SAPs incorporating bioactive ligands or focused moieties, especially in cancer therapy.

Notwithstanding these developments, several problems still exist, such as restricted influence over prolonged drug release, possible toxicity of synthetic constituents, and problems with scaling for clinical applications. The development of biocompatible, biodegradable, and multipurpose SAP systems with exact control over drug delivery pharmacokinetics and targeting efficiency is thus the focus of current research.

3. Significance of the Study:

The disadvantages of traditional drug delivery methods, such as low bioavailability, non-specific dispersion, quick degradation of drugs, and frequent dosing, are addressed in this important work. Superabsorbent polymers (SAPs) offer an efficient platform for regulated and prolonged drug release, increasing therapeutic efficacy and minimising side effects because of their significant swelling capacity and hydrogel-making capabilities[1].
The creation of stimuli-responsive SAPs, which may release medications in reaction to physiological indicators like pH and temperature, is a crucial component of this research. This improves medication efficacy while reducing systemic toxicity by enabling targeted and location-specific drug delivery[2].

To attain the ideal harmony between biodegradability, biocompatibility, and mechanical strength, all crucial for secure and reliable drug delivery systems, the study also focuses on blending synthetic and natural polymers[12]. All things considered, this research advances effective, affordable, and patient-friendly drug delivery systems, which may find use in personalised medicine and the treatment of chronic illnesses.

4. Research Gap:

- **Limited control over burst release:** Many SAP systems exhibit an initial rapid drug release, reducing therapeutic efficacy and potentially causing side effects.

- **Inadequate mechanical strength:** Highly swollen SAP hydrogels often lack sufficient structural stability, limiting their application in injectable and implantable systems.

- **Poor precision in stimuli-responsiveness:** Existing pH- or temperature-responsive SAPs may not accurately match complex physiological conditions, especially in targeted delivery (e.g., colon-specific systems).

- **Biocompatibility and toxicity concerns:** Residual monomers and synthetic crosslinkers can cause cytotoxicity, thereby restricting clinical translation.

5. Objectives of this research:

- To design and develop **stimuli-responsive superabsorbent biopolymer-based hydrogel systems** for controlled and targeted drug delivery.

- To assess and optimise the swelling ratio, crosslinking density, mechanical strength and water retention capabilities of the composite hydrogel under various pH and temperature conditions to determine its suitability for controlled drug release and to characterise the SAP using different thermal, spectroscopic and morphological techniques to confirm surface morphology, functional group incorporation, and elemental distribution.

- To evaluate the drug loading and in vitro drug release of the hydrogel in simulated physiological conditions, and to evaluate its potential for sustained drug delivery.

- To assess biocompatibility and toxicity by performing cytotoxicity and compatibility studies.

6. Methodology:

The proposed research will involve the **synthesis, characterisation**, and **evaluation** of SAP-based drug delivery systems through a systematic experimental approach.

Materials

This study utilises hydrophilic monomers like acrylamide, natural polymers like pullulan or chitosan, and crosslinking agents like N, N'-methylenebisacrylamide (MBA). For polymerisation, initiators like ammonium or potassium persulphate (APS or KPS) are required. The targeted delivery method will determine which model drugs, hydrophilic or hydrophobic, are chosen.

Synthesis of Superabsorbent Polymers

The free radical polymerisation method will be used to create SAPs. First, a uniform mixture of monomers and the polymeric backbone will be made while being continuously stirred. After adding the crosslinking agent to create a network structure, dissolved oxygen will be eliminated by purging with nitrogen gas. To start polymerisation, the initiator (KPS or APS) will be added. Until gel formation takes place, the resultant mixture will be kept at a regulated temperature (between 50 and 70°C). The resultant hydrogel will be dried to produce SAP particles after being extensively cleaned to get rid of unreacted monomers.

Drug Loading

The following techniques will be used to load drugs:

- The **swelling-diffusion approach** or **ex-situ loading** involves submerging dried SAP in a medication solution until equilibrium swelling is achieved.
- Drug incorporation during polymer production is known as **in-situ loading.**

Standard analytical techniques, such as UV-Vis spectroscopy, will be used to calculate **drug loading** and **drug encapsulation efficiency**.

Characterisation of SAPs

The synthesised SAPs will be characterised using various analytical techniques:

- **Fourier Transform Infrared Spectroscopy (FTIR):** To identify functional groups and confirm polymer formation

- **Scanning Electron Microscopy (SEM):** To study surface morphology and porosity
- **X-ray Diffraction (XRD):** To analyse crystallinity
- **Thermogravimetric Analysis (TGA):** To determine thermal stability
- **UV-Visible Spectroscopy:** To monitor drug loading and release behaviour.

Swelling Study:

To ascertain equilibrium swelling capacity, swelling behaviour will be assessed in multiple media (distilled water, buffered solutions with varied pH values). To evaluate stimulus-responsive behaviour, the impact of pH levels and ionic strength on expansion will be examined.

$$\text{Swelling Ratio (\%)} = \frac{(w_s - w_d)}{w_d} * 100$$

where w_s refers to swollen hydrogel, and w_d refers to dry hydrogel.

Sol-Gel Content:

To determine the hydrogel's cross-linked fraction, we use the sol-gel method. The **crosslinked, insoluble** part of the polymeric network that is still present even after extraction in a solvent is known as **gel fraction** or **gel content.** The **unreacted, soluble** part of the polymeric network that dissolves out during extraction is called the **sol fraction** or **sol content.**

$$\text{Sol Fraction} = \frac{W_1 - W_2}{W_1} * 100$$

$$\text{Gel Fraction} = 100 - \text{Sol Fraction}$$

Porosity:

The term "porosity" describes the existence of void spaces or pores in the three-dimensional polymeric network of a hydrogel. The amount of fluid that a hydrogel material can take in, store, and transport is determined by this crucial structural characteristic. The percentage of the hydrogel's total volume that is made up of void spaces, or pores, as opposed to solid polymer, is known as porosity.

$$\text{Porosity} = \frac{Volume\ of\ pores}{Total\ volume\ of\ the\ hydrogel} * 100$$

Drug Loading and Drug Entrapment Efficiency:

Drug loading capacity can be defined as the amount of drug loaded inside the hydrogel disc relative to the initial weight of the hydrogel disc before loading of the drug.

$$\%\text{Drug Loading (\%DL)} = \frac{W_f - W_i}{W_i} * 100$$

Where w_f refers to the weight of the drug-loaded hydrogel disc and w_i refers to the initial weight of the hydrogel disc.

Drug entrapment efficiency is an important parameter to assess how effectively the drug molecule is entrapped within the hydrogel matrix during its formation in the case of in-situ drug loading.

$$\text{Drug Entrapment Efficiency (\%DEE)} = \frac{Drug\ amount\ in\ the\ hydrogel}{Theoretical\ drug\ amount\ in\ the\ hydrogel\ disc} * 100$$

Cumulative Drug Release

Cumulative Drug Release refers to the total amount of drug released over various time periods, represented as a percentage of the original total drug amount.

$$\text{Cumulative Drug Release (\%)} = \frac{A_t}{A_o} * 100$$

Where A_t shows the amount of drug released up to time 't' and A_O represents the amount of drug loaded in the hydrogel.

Studies on drug release will be carried out under physiologically mimicked settings (e.g., intestinal pH ~6.8-7.4 and stomach pH ~1.2). Samples will be taken out on a regular basis and subjected to UV-Vis spectroscopic analysis. Models like the zero-order, first-order, Higuchi, and Korsmeyer-Peppas models will be used to assess release kinetics.

Biocompatibility Assessment:

For superabsorbent polymer (SAP)-derived drug delivery systems to be safe for use in biomedical applications, biocompatibility is a crucial prerequisite. Standard in-vitro methods will be used to assess the produced polymers' **hemocompatibility, cell compatibility**, and **cytotoxicity**.

7. Expected Outcome of the Research:

- A **well-designed, stimuli-responsive hydrogel system** capable of responding to physiological triggers (pH, temperature, or enzymes)
- Achievement of **sustained and controlled drug release profiles** over an extended period.
- Development of SAP hydrogels with improved **structural integrity** even after swelling.
- Improved **drug retention and stability** within the polymeric network.
- Minimal cytotoxicity and improved **biological compatibility.**

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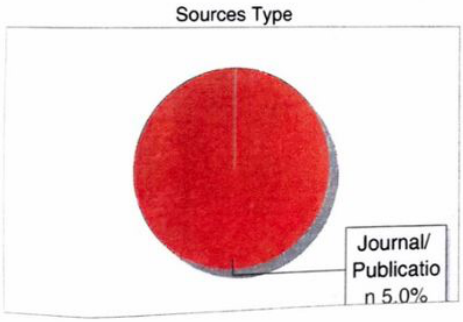

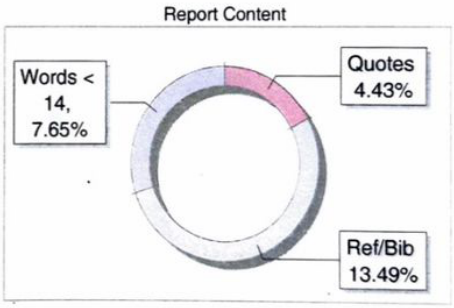

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Department of Sciences (Chemistry)

Dr. Sudhir G. Warkar
Professor
Department of Applied Chemistry
Delhi Technological University

Department of Sciences (Chemistry)
School of Sciences

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ABSTRACT

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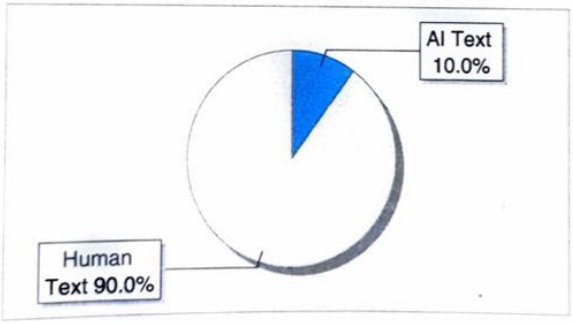

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